REMARKS

Applicants have reviewed and considered the Office Action mailed on October 4, 2004, and the references cited therewith.

In the specification, the paragraph beginning on page 8, line 9, of the application has been amended to correct a minor editorial problem.

In the claims, claim 10 has been amended to correct an editorial problem. No claims are canceled or added. As a result, claims 1-14 remain pending in the application.

Applicants hereby request further examination and reconsideration of the application, in view of the following remarks.

Information Disclosure Statement Issues

(1). Applicants point out that all patents, publications, or other information submitted for consideration by the Office have been included in "a separate paper," specifically in a 1449 form, as required by MPEP § 609(A)1. (*Contra* Office Action mailed October 4, 2004, ¶ 1, lns. 1-4). Notably, all references referred to in the specification are included in the 1449 form. Accordingly, consideration by the Examiner of the references in the 1449 form is respectfully requested.

(2). Applicants' information disclosure statement filed November 11, 2003 currently stands unconsidered by the Examiner for "fail[ing] to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance . . . of each patent listed that is not in the English language." (Office Action mailed October 4, 2004, ¶ 2, lns. 1-5). In response, Applicants have attached (to this paper) the information disclosure statement of November 11, 2003 along with concise explanations of the relevance of each patent listed therein which is not available in the English language. Accordingly, consideration by the Examiner of the references in the 1449 form is respectfully requested.

Pursuant to the provisions of MPEP § 609, Applicants further request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

§102 Rejection of the Claims

(3-4). Claims 1-14 were rejected under 35 USC § 102(e) for anticipation by Segal et al. (U.S. Patent No. 6,402,207, which is also referred to herein as the " '207 Patent") or Segal et al. (U.S. Patent No. 6,612,624, which is also referred to herein as the " '624 Patent"). Applicants respectfully traverse.

As an initial note, Applicants do not admit that Segal et al. ('207 Patent) or Segal et al. ('624 Patent) are prior art and reserve the right to swear behind them at a later date as provided under 37 CFR § 1.131. Nevertheless, Applicants believe that claims 1-14 are distinct over Segal et al. ('207 Patent) and Segal et al. ('624 Patent) for the reasons stated below.

Anticipation requires the disclosure in a single prior art reference of *each element* of the claim under consideration. *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897, 1908 (Fed. Cir. 1990)(en banc)(emphasis added), cert. denied, 500 U.S. 904 (1991). The abstract of a patent application may be used for interpreting the scope of such patent's claims. *See Hill Rom Co. v. Kinetic Concepts, Inc.*, 209 F.3d 1337, 1341 n.*, 54 USPQ2d 1437, 1440 n.1 (Fed. Cir. 2000)); 35 CFR § 1.72(b).

Applicants respectfully submit that the Office Action has not made out a *prima facie* case of anticipation because the references do not teach each and every claim element.

Neither reference teaches each and every claim element:

Claims 1-14:

The Office Action states:

> Both Segal et al. references teach fastening mechanism *for* medical instruments such as a syringe having portion 1 and portion 3, portion 1 having a flange or collar (55) and connector portion 3 having connector 50 each of which are collectively *attached to their respective medical syringe devices*. . . . In the least, please *note columns 4-6.*

(Office Action, ¶ 4, lns. 2-7)(emphasis added).

In noting columns 4-6 of either Segal et al. reference ('207 Patent; '624 Patent), Applicants come across many significant assertions. As one example, it is stated that "portion [1] terminates in a flange or collar **55** adapted *to connect with* a fluid receiving or delivering device." ('207 Patent, col. 4, ln. 67 - col. 5, ln. 1; '624 Patent, col. 4, lns. 51-52)(emphasis added). As another example, it is stated that "connector [3] *terminates in* a chamfered end **70**

having *an axially extending connector* **50**." ('207 Patent, col. 5, lns. 9-10; '624 Patent, col. 4, lns. 61-62)(emphasis added). As yet another example, it is stated that "[e]ach medical connector portion **1**, **3** has an end **55**, **50** opposite the mating surface or ends **20**, **30** that are adapted *to mate to* a fluid delivering device." ('207 Patent, col. 5, lns. 47-49; '624 Patent, col. 5, lns. 31-33)(emphasis added). Thus, the Office Action apparently takes the position that the medical connector disclosed in Segal et al. ('207 Patent; '624 Patent) is a device distinct from medical instruments, such as a syringe.

Unlike the claimed invention, the device described by Segal et al. ('207 Patent; '624 Patent) does not include a first syringe *including* a first syringe tip with a male end portion, wherein the male end portion has a locking ring and a tip, as recited in claim 1. Further, the device described by Segal et al. ('207 Patent; '624 Patent) does not include a second syringe *including* a second syringe tip with a female end portion, wherein the female end portion comprises one or more exteriorly protruding members adapted to detachably fit the locking ring, as recited in claim 1. Consequently, the Segal et al. ('207 Patent; '624 Patent) device also does not disclose or suggest a female end portion of a second syringe having an opening therein, the opening sized and configured to receive the tip of the male end portion of a first syringe therein, as further recited in claim 1.

Moreover, Segal et al. ('207 Patent; '624 Patent) provides no teaching that would have suggested the desirability of configuring a first syringe to couple directly to a second syringe as claimed in the instant invention. Referring to column 6 of either Segal et al. reference, as directed by the Office Action, it is stated that "the ends opposite the mating surfaces **60A**, **62A** . . . allow the device to be inserted *between the patient and the injection, infusion, or evacuation source.* ('207 Patent, col. 6, lns. 22-25; '624 Patent, col. 6, lns. 6-9)(emphasis added). Similarly, it is stated in the abstract that "*one side* of [the medical connector] . . . *attaches to the infusion source* and the *other side* of [the medical connector] . . . *is coupled* . . . *to the patient.* ('207 Patent, Abstract, lns. 3-6; '624 Patent, Abstract, lns. 3-6)(emphasis added).

Claims 2-14 are dependent on claim 1 and are patentable over Segal et al. ('207 Patent and '624 Patent) for the reasons argued above, plus the elements in such claims. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 102 basis of rejection of claims 1-14.

Common Ownership

(6). Applications and references (whether patents, patent applications, patent application publications, etc.) will be considered to be owned by, or subject to an obligation of assignment to, the same person, at the time the invention was made, if the applicants or the applicants' attorney or agent of record makes a statement to the effect that the application and the reference were, at the time the invention was made, owned by, or subject to an obligation of assignment to, the same person. (Official Gazette Notice, 1241 OG 96 (Dec. 26, 2000)).

Applicants assert that claims 1-14 were commonly owned at the time any inventions covered therein were made.

§103 Rejection of the Claims

(5,7). Claims 1-14 were rejected under 35 USC § 103(a) as being unpatentable over Chu (U.S. Patent No. 4,743,229, which is also referred to herein as the " '229 Patent") in view of Kanno (U.S. Patent No. 4,629,455, which is also referred to herein as the " '455 Patent"). Applicants respectfully traverse.

The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d (BNA) 1596, 1598 (Fed. Cir. 1988); *In re Piasecki*, 745 F.2d at 1472, 223 U.S.P.Q. at 788. If the examiner does not establish a *prima facie* case, the applicant is under no obligation to submit evidence of non-obviousness. MPEP § 2142. Applicants respectfully submit that the Office Action fails to make out a *prima facie* case of obviousness on at least three grounds.

First, the references when combined must teach or suggest *all* the claim elements. MPEP § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991))(emphasis added). *See In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970) (stating "*all words* in a claim must be considered in judging the patentability of that claim against the prior art.")(emphasis added). The elements must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Second, there must be a basis in the art for combining or modifying references. *See In re Geiger*, 815 F.2d at 688, 2 USPQ2d at 1278 (Fed. Cir. 1987). The mere fact that references can be combined or modified does not render the resultant combination obvious, unless the prior art also suggests the desirability of the combination. *In re Kotzab*, 217 F.3d 1365, 1371, 55

USPQ2d 1313, 1318 (Fed. Cir. 2000); *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). A teaching or suggestion to make a claimed combination and a reasonable expectation of success must both be found in the prior art, not in the applicants' disclosure. *In re Vaeck* at 493; MPEP § 2143.01. The examiner must avoid hindsight. *In re Bond* at 832.

Third, the examiner must provide a *specific reason* to support an obvious rejection. *Ex parte Humphreys*, 24 USPQ2d 1255 (BPAI 1992)(emphasis added). An examiner's assertion that a modification proposed is "an obvious matter of engineering design choice" is an unsupported conclusion - not a reason upon which to base a rejection. *See In re Garrett*, 33 BNA PTCJ 43 (November 13, 1986); *see also In re Gal*, 980 F.2d 717, 25 USPQ2d 1076 (Fed. Cir. 1992)(rejecting an "obvious design choice" rejection wherein the claimed structure and its function are different from the prior art); *see also In re Chu*, 66 F.3d 292, 36 USPQ2d 1089 (Fed. Cir. 1995)(rejecting an "obvious design choice" rejection wherein there is no teaching or suggestion in the reference to modify its own structure in the manner of the rejected claim).

The references relied upon do not teach or suggest all the limitations of the claims:

Claims 1-14:

Applicants note that the Office Action states:

> Chu teaches all of the limitations of the claims *except for* explicitly reciting *the locking ring* being *rotatably coupled with the male end portion*. Kanno teaches a *rotatably coupled locking ring* mounted on a medical instrument. It would have been obvious to one of ordinary skill in the art, at the time of invention to have *modified the connecting structure* of Chu with the connecting member as taught by Kanno.

(Office Action mailed October 4, 2004, ¶ 7, lns. 2-6)(emphasis added). Thus, the Office Action apparently takes the position that Chu fails to disclose each and every limitation of claim 1, including a "locking ring being rotatably coupled with the male end portion." (Id., ¶ 7, ln. 3). However, the Office Action believes that Kanno teaches the missing limitations. (Id., ¶ 7, ln. 4).

Claim 1 recites:

> A coupling syringe system comprising:
> *a first syringe including* a first syringe barrel having a first syringe open proximal end and a first syringe distal end, the first syringe further including *a first syringe tip with a male end portion wherein the male end portion has a locking ring and a tip*, the first syringe barrel having a first syringe inner surface;

a first syringe plunger slidably disposed within the first syringe barrel, the first syringe plunger in fluid-tight engagement with the first syringe inner surface;

a second syringe including a second syringe barrel having a second syringe open proximal end and a second syringe distal end, the second syringe further including *a second syringe tip with a female end portion wherein the female end portion comprises one or more exteriorly protruding members adapted to detachably fit the locking ring*, the second syringe barrel having a second syringe inner surface;

a second syringe plunger slidably disposed within the second syringe barrel, the second syringe plunger in fluid-tight engagement with the second syringe inner surface;

the female end portion having an opening therein, the opening sized and configured to receive the tip of the male end portion therein;

wherein the locking ring couples the first syringe to the second syringe when the tip of the male end portion is disposed within the female end portion, forming a fluid tight engagement.

(Applicants' claim 1)(emphasis added).

Unlike the claimed invention, Chu describes a separate connector means **50** which is used to connect a first syringe **12** to a second syringe **14**. ('229 Patent, col. 4, lns. 45-52). FIG. 2 clearly establishes that the connection means **50** is an element not integrated with (e.g., separate element from) either the first syringe **12** or the second syringe **14**. (*See* FIG. **2** of '229 Patent). Modifying the connecting structure of Chu with the connection member as taught by Kanno, as suggested by the Office Action, also results in a connection element not integrated with either the first syringe **12** or the second syringe **14** (e.g., the connection element remains a *separate element* positioned *between* the first syringe **12** and the second syringe **14**).

Thus, the references (even when combined) do not teach or suggest "a first syringe *including* . . . a first syringe tip with a male end portion wherein the male end portion has a locking ring and a tip, . . . a second syringe *including* . . . a second syringe tip with a female end portion wherein the female end portion comprises one or more exteriorly protruding members adapted to detachably fit the locking ring, . . . *wherein the locking ring couples the first syringe to the second syringe when the tip of the male end portion is disposed within the female end portion*" as recited in Applicants' claim 1 (emphasis added). In other words, the Applicants' claimed invention does not require a separate (e.g., non-integrated) connection element to be positioned between the first syringe and the second syringe or a discharge assembly to establish a connection between such devices.

Claims 2-14 are dependent on claim 1 and are patentable over Chu ('229 Patent) in view of Kanno ('455 Patent) for the reasons argued above, plus the elements in such claims.

Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103 basis of rejection of claims 1-14.

There is no suggestion or incentive to modify or combine the references:

Claims 1-14:

The Office Action must identify a teaching in the prior art that would have suggested the desirability of combining the limitations, e.g., a "motivation" to modify the connecting structure of Chu with the connecting member as taught by Kanno; however, no such teaching has been provided.

Chu describes a first adapter **42** located at an end **18** of a first syringe **12** and a second adapter **44** located at an end **24** of a second syringe **14**. ('229 Patent, col. 4, lns. 45-48). Chu states that "these adapters are preferably male Luer connectors which may be provided with internal threads." (Id., col. 4, lns. 48-50). "The adapters are joined by connector means **50** which is preferably a female Luer connector. End ridges **52** and **54** of the female Luer connector are adapted to fit within the threads **46** and **48** of the male Luer connector." (Id., col. 4, lns. 50-54). Chu further describes an alternative embodiment in which "threads **46** and **48** may be replaced by an internal groove which provides a "snap"-type connection with female Luer connector **50**." (Id., col. 4, lns. 55-57). In sum, Chu describes two male/female connection schemes which may firmly join a first device to a second device and makes no mention of a need for additional male/female connection alternatives.

Accordingly, one of ordinary skill in the art would have had no reason to consider additional male/female connection alternatives to make a connection between two devices, such as a first syringe and a second syringe or discharge assembly. Rather, one of ordinary skill would have appreciated the desirability of a male/female connection utilizing an integrated locking ring to join a first syringe to a second syringe or discharge assembly only upon access to the Applicants' disclosure, which is impermissible. For this reason, Applicants respectfully request withdrawal of the 35 U.S.C. § 103 basis of rejection of claims 1-14.

No specific reason was provided to support an obviousness rejection:

Claims 1-14:

The Office Action must provide a specific reason to support an obvious rejection, e.g., a reason which is clear and particular and not a broad conclusory statement; however, no such reason has been provided. The Office Action merely infers that modifying the connecting structure of Chu with the connecting member as taught by Kanno would have been an obvious alternative design choice to establish a firm connection between a male and female connection. (*See* Office Action mailed October 4, 2004, ¶ 7, lns. 4-8). Applicants respectfully submit that the Examiner has not produced a specific reason to support an obvious rejection; accordingly, Applicants request withdrawal of the 35 U.S.C. § 103 basis of rejection of claims 1-14.

CONCLUSION

In view of the above, Applicants respectfully submit that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 359-3261 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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By their Representatives,

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Date 12/30/04

By _____
Gary J. Speier
Reg. No. 45,458

Attachments

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 30th day of December, 2004.

Dawn M. Poole
Name

Dawn M. Poole
Signature

APPENDIX

This **Appendix** includes the following:

(1) A copy of the Information Disclosure Statement (IDS), originally filed on November 11, 2003 for the above-identified application (consists of 7 pages); and

(2) Concise explanations of the relevance of each foreign patent listed within the IDS, as some may not be available in the English language.